## REMARKS

This Amendment is responsive to the Office Action dated July 8, 2008. Applicant has added claim 32. Claims 1-32 are pending.

### Claim Rejection Under 35 U.S.C. §§ 102/103

In the Office Action, the Examiner rejected claims 1–3, 7–8, 15–19, 21, 24, and 27–31 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Kramer et al. (US 5,405,362, herein referred to as "Kramer"). Applicant respectfully traverses the rejection. Kramer fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested a rational reason for modification to include such features.

With respect to independent claim 1, Kramer fails to disclose or suggest a method in which a device automatically determines a magnitude at which to supply pacing stimuli, based, at least in part, upon an analysis of patient physical parameters performed by the device. Similarly, Kramer fails to disclose or suggest an external medical device comprising a controller configured to automatically determine a magnitude at which to supply pacing stimuli, based, at least in part, upon an analysis of patient physical parameters which is performed by the controller, as required by independent claims 24 and 30. With respect to independent claim 31, Kramer also fails to disclose or suggest a method comprising automatically determining in a processor a magnitude at which to supply pacing stimuli, based, at least in part, on a determination by the processor of whether the device previously provided a defibrillation shock to the patient.

Kramer does not disclose or suggest automatically determining a pacing magnitude. In support of the rejection of independent claims 1, 24, 30, and 31, the Office Action characterized Kramer's description of "predetermined selectable quantities . . . used to transcutaneously pace a patient's heart in a manner consistent with selective control signals and instructions from the CPU," as teaching automatically determining a pacing magnitude.[1] However, this portion of Kramer does not disclose or suggest that the CPU automatically determines a pacing magnitude. Rather, an *operator* may select one of the predetermined selectable quantities, and the CPU may generate control signals based on the *operator*-selected magnitude.

[1] Kramer, column 14, lines 13-23.

Additionally, Kramer states "the control signal generated by the CPU to regulate the transcutaneous pacing is indicative of the P wave, the QRS complex, the R wave, atrial contraction, and/or ventricular contraction of a patient's heart.[2]" However, Kramer does not disclose or suggest that the pacing magnitude is based on any of these parameters. Instead, the CPU may monitor these parameters to deliver pacing when these parameters indicate pacing is needed, as is commonly done in demand pacing applications. In other words, regulating transcutaneous pacing based on the QRS complex, the R wave, atrial contraction, and/or ventricular contraction of a patient's heart is suggesting of regulating pacing rate, rather than magnitude. Kramer does not state that pacing magnitude is regulated based on these parameters.

The Examiner also characterized Kramer's expert system as automatically determining a pacing magnitude. However, Kramer describes that the treatment and diagnostic algorithms of the expert system receive input data from a human operator and generate instructions to the human operator.[3] Nothing in Kramer discloses or suggests that the expert system automatically generates a pacing magnitude, much less does so based on an analysis of patient parameters performed by the expert system. Rather, the expert system may receive an input from the human operator defining the pacing magnitude.

The Examiner also stated that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system as taught by Kramer with eliminating system dependency on user input by making the system automatic. The Office Action reasoned that such a modification would provide the predictable result of providing quicker therapy by eliminating an intermediate step and providing greater patient safety by removing human error. The Office Action also cited *In re Venner* as teaching that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.

Applicant respectfully disagrees with the Office Action's assertion that it would have been obvious to automate the system taught by Kramer. Kramer is directed to an interactive external defibrillation and drug injection system for use by a human operator for treating cardiac conditions in a patient.[4] Since Kramer stresses an interactive system, a person of ordinary skill in

[2] Kramer, column 14, lines 13-23.
[3] Kramer, column 11, lines 35-40.
[4] Kramer, column 3, lines 64-67.

the art would have recognized that the modification suggested by the Office Action would have eliminated the advantages provided by Kramer with respect to operator control.

The Office Action cited *In re Venner* for the proposition that it is generally known or desirable to automate a previously manual process. However, even with such a general knowledge or desire, a person of ordinary skill in the art would not have considered it obvious to automate a process whose stated advantage and objective is the provision of operator control. Thus, even with such a general knowledge or desire, a person of ordinary skill in the art would not have considered it obvious to modify the Kramer system to eliminate system dependency on user input by making the system automatic.

Kramer also fails to disclose or suggest the requirements of claims 2, 3, 15-19, 21, and 27-29. Each of claims 2, 3, 15-19, 21, and 27-29 depends on one of independent claims 1, 24, 30, and 31. For at least the reasons described above with respect to the independent claims, claims 2, 3, 15-19, 21, and 27-29 are also in condition for allowance.

Additionally, with respect to claim 7, Kramer fails to disclose or suggest that the step of obtaining and analyzing comprises determining whether a defibrillation shock has been delivered to the patient within a predetermined period of time. The Office Action cited block 420 of the flowchart illustrated in FIG. 18B as teaching this requirement. However, the determination of whether or not a shock has been delivered, as outlined in FIG. 18B, is not relevant to determining whether a patient's heart condition is treatable though defibrillation or pacing, as required by claim 7. Instead, Kramer's determination of shock delivery is used to inform a user that the shock was delivered or that the shock was aborted.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1–3, 7–8, 15–19, 21, 24, and 27–31 under 35 U.S.C. §§ 102(b) and 103(a). Withdrawal of this rejection is requested.

**Claim Rejection Under 35 U.S.C. § 103**

The Office Action rejected claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Kramer in view of Kroll et al. (US 6,167,306, herein referred to as "Kroll"); rejected claims 4–5, 8–17, 20, 23, and 25–26 under 35 U.S.C. § 103(a) as being unpatentable over Kramer in view of Snyder et al. (US 6,356,785, herein referred to as "Snyder"); rejected claim 22 under 35 U.S.C. §

103(a) as being unpatentable over Kramer in view of Snyder and further in view of Sherman et al. (US 2001/0018562, herein referred to as "Sherman"). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

With respect to claims 9 and 25, the applied references fail to disclose or suggest causing the device to perform the steps of automatically adjusting the magnitude and pacing rate to an updated magnitude and updated pacing rate based, in part, on the updated physical parameters and supplying the pacing stimuli to the patient at the updated magnitude and at the updated pacing rate. In contrast, Snyder's FIG. 15, which was cited by the Office Action, illustrates periodically monitoring a patient's blood oxygen level to determine if CPR should continue. Snyder's FIGS. 16B and 17B, which were also cited by the Office Action, illustrate patient monitoring to determine if the diagnosis has changed. The Office Action's assertion that Snyder teaches adjusting the pacing stimulus based on updated parameters is incorrect. The portions of Snyder cited by the Office Action relate to determining whether a therapy should continue or whether a different therapy should be used. The applied references fail to disclose or suggest adjusting the magnitude and pacing rate based, in part, on the updated physical parameters.

The applied references also fail to disclose or suggest that the step of indicating to a user that non-electrotherapeutic treatment is needed includes prompting the user to monitor the patient's $SaO_2$ level, as required by claim 20. The Office Action failed to address the specific requirements of claim 20. For example, the Office Action has not identified a reference that teaches prompting the user to monitor the patient's $SaO_2$ level. Applicant requests that the requirements of claim 20 are addressed in any subsequent Office Action.

The applied references also fail to disclose or suggest that the step of identifying an indication to cease the pacing includes identifying no electrical capture, no mechanical capture, failure in improvement of cardiac output, or adequate spontaneous circulation, as required by claims 11-14, respectively. The Office Action acknowledged that neither Kramer nor Snyder disclose or suggest the requirements of claims 11-14. However, the Office Action reasoned that it would have been obvious to modify the system of Kramer in view of Snyder to monitor the parameters required by claims 11-14, because using the claimed parameters to provide an

indication of whether pacing would be beneficial or detrimental is known in the art. Applicant respectfully disagrees with this assertion.

Claims 11-14 each depend upon claim 10. In support of the rejection of claim 10, the Office Action cited portions of Snyder that describe making a revised diagnosis and delivering a different therapy to treat the newly diagnosed condition if the patient data changes and ceasing therapy if normal cardiac function is detected.[5] Snyder only contemplates ceasing therapy delivery if normal cardiac function is detected and does not disclose or suggest any other method of evaluating or ceasing pacing. Therefore, it is unclear why one of ordinary skill in the art would have been motivated to identifying no electrical capture, no mechanical capture, failure in improvement of cardiac output, or adequate spontaneous circulation to cease pacing.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 4–6, 8–17, 20, 22, 23, and 25–26 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

**New Claims:**

Applicant has added claim 32 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claim 32, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose or suggest a method comprising causing a device to automatically determine a magnitude at which to supply pacing stimuli, based, at least in part, upon an analysis of patient physical parameters performed by the device, wherein the physical parameters comprise at least one of electrocardiogram, presence of electrical capture, presence of mechanical capture, cardiac output, blood flow, blood pressure, or impedance, as recited by new claim 32. No new matter has been added by the new claims.

[5] Snyder, column 17, lines 10-18 and column 21, lines 36-39.

## CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

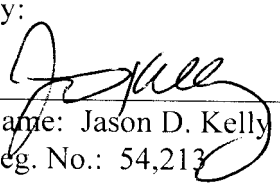
In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references, or the Examiner's findings with respect to the effective filing date of any claims in this application. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

October 7, 2008

By:



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